B. Annual Reports. Serono shall submit to OIG annually a report with respect to the status of, and findings regarding, Serono's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (*e.g.*, change in contractor policy) and copies of any compliance-related Policies and Procedures;

3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

5. a description of any changes to the records collected, tracked, and maintained pursuant to Section III.D.1.a;

6. a description of any changes to the internal review and approval process required by Section III.D.1.g;

7. a description of any changes to the documentation, recordkeeping, and review procedures and other Arrangements Procedures required by Section III.D.1;

8. a list of the parties with whom Serono entered or renewed Educational Sponsorship Arrangements during the Reporting Period; a description of the aggregate number of Educational Sponsorship Arrangements that Serono entered with each particular individual or entity during the Reporting Period; and a description of the aggregate amount of funding provided by Serono to each individual or entity provider of Educational Activities during the Reporting Period;

9. a complete copy of all Reports prepared pursuant to Section III.F, along with a copy of the IRO's engagement letter (if applicable);

10. Serono's response and corrective action plan(s) related to any issues raised by the Reports prepared pursuant to Section III.F;

11. a summary and description of any and all current and prior engagements and agreements between Serono and the IRO, if different from what was submitted as part of the Implementation Report;

12. a certification from the IRO regarding its professional independence and/or objectivity with respect to Serono;

13. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

14. a summary of the disclosures in the disclosure log required by Section III.G that relate to Federal health care programs or to FDA requirements;

15. any changes to the process by which Serono fulfills the requirements of Section III.H regarding Ineligible Persons;

16. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.H; and the actions taken by Serono in response to the screening and removal obligations set forth in Section III.H;

17. a summary describing any ongoing investigation or legal proceeding

required to have been reported pursuant to Section III.I. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

18. a summary describing any ongoing communication with the FDA required to have been reported pursuant to Section III.K. The summary shall include a description of the matter, and the status of such matter;

19. as required by Section III.L, a copy of Serono's Off-Label Findings, the underlying records reflecting the content of detailing sessions between HCPs and Covered Persons, and a description of responsive action(s), if any, taken by Serono in connection with its Off-Label Findings;

20. a summary describing any Serostim Inquiry Report(s) indicating that an undue or unusual number of requests for off-label information has been generated in any particular sales territory or that otherwise suggest that improper off-label promotion may have occurred, the Compliance Officer's review and inquiry into any such occurrence(s), and the results and resolution of the matter;

21. a list and description of all actively promoted Serono products and, if available from third parties or other sources, information about the estimated relative usage (*e.g.*, the percentage) of those products for off-label purposes.

22. a description of all changes to the most recently provided list of Serono's locations (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Serono currently submits claims (if any);

23. a description of Serono's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

24. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Serono is in compliance with all of the requirements of this CIA;

2. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful;

3. if applicable, Serono has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

4. Serono's: (a) Policies and Procedures as referenced in Section III.B.2 above; (b) training materials used for purposes of Section III.C, above; (c) standard form or template contracts; (d) materials for training personnel on product education and promotion; and (e) promotional materials containing claims about Serono's products, have been reviewed by Serono's legal counsel and have been found to be in compliance with all applicable Federal health care program requirements and FDA Advertising and Promotional Requirements;

5. to the best of his or her knowledge, Serono has implemented procedures reasonably designed to ensure that all Educational Sponsorship Arrangements do not violate the Federal anti-kickback statute or FDA Sponsorship Requirements, including the Arrangements Procedures required in Section III.D of the CIA; and

6. to the best of his or her knowledge, Serono has fulfilled the requirements for New and Renewed Arrangements under Section III.D.2 of the CIA.

D. Designation of Information. Serono shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure

under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Serono shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be made in writing and submitted to the following entities:

OIG:
Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Serono:
Robert A. Freeman
U.S. Compliance Officer and Compliance Counsel
Serono, Inc.
1 Technology Place
Rockland, MA 02370
Telephone: 781.681.2490
Facsimile: 781.681.2933

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Serono's books, records, and other documents and supporting materials and/or conduct on-site

reviews of any of Serono's locations for the purpose of verifying and evaluating: (a) Serono's compliance with the terms of this CIA; and (b) Serono's compliance with the requirements of the Federal health care programs in which it participates and with applicable FDA requirements. The documentation described above shall be made available by Serono to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction.

Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Serono's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Serono shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Serono's employees may elect to be interviewed with or without a representative of Serono present.

VIII. DOCUMENT AND RECORD RETENTION

Serono shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Serono prior to any release by OIG of information submitted by Serono pursuant to its obligations under this CIA and identified upon submission by Serono as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Serono shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

A breach of this CIA does not constitute a breach of the Settlement Agreement between Serono and the United States or the settlement agreements with individual states referred to in the Preamble. Any breach of the terms of those agreements does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of the CIA. Section X of this CIA specifies all of the remedies available to the OIG if Serono fails to satisfy its obligations under this CIA. The remedies available to the OIG under this Section X do not preempt or limit any actions that individual States may take against Serono under appropriate authorities.

Serono is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Serono and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Serono fails to establish and implement any of the following obligations as described each corresponding subsection of Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. the training of Covered Persons;

f. the Arrangements Procedures and/or Arrangements Requirements described in Sections III.D.1 and III.D.2;

g. a Disclosure Program;

h. Ineligible Persons screening and removal requirements;

i. notification of Government investigations or legal proceedings;

j. notification of communications regarding off-label related matters;

k. a review of records reflecting the content of detailing sessions; and

l. monitoring and review of requests for off-label information.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Serono fails to engage an IRO, as required in Section III.F and Appendices A-B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Serono fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Serono fails to submit the Report associated with any of the Reviews in accordance with the requirements of Section III.F and Appendices A-B.

5. A Stipulated Penalty of $1,500 for each day Serono fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Serono fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Serono as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Serono fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Serono, stating the specific grounds for its determination that Serono has failed to comply fully

and adequately with the CIA obligation(s) at issue and steps Serono shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Serono receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Serono may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Serono fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Serono receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Serono has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Serono of: (a) Serono's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter"). Such Demand Letter shall state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after receipt of the Demand Letter, Serono shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Serono elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Serono cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material

breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Serono has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

a. a failure by Serono to report a Reportable Event and take corrective action as required in Section III.J.2;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.F and Appendices A-B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Serono constitutes an independent basis for Serono's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Serono has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Serono of: (a) Serono's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Serono shall have 30 days from the date of receipt

of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Serono is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Serono has begun to take action to cure the material breach; (ii) Serono is pursuing such action with due diligence; and (iii) Serono has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Serono fails to satisfy the requirements of Section X.D.3, OIG may exclude Serono from participation in the Federal health care programs. OIG shall notify Serono in writing of its determination to exclude Serono (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Serono's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Serono may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

1. *Review Rights.* Upon OIG's delivery to Serono of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Serono shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after

receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Serono was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Serono shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Serono to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Serono requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether Serono was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Serono had begun to take action to cure the material breach within that period; (ii) Serono has pursued and is pursuing such action with due diligence; and (iii) Serono provided to OIG within that period a reasonable timetable for curing the material breach and Serono has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Serono, only after a DAB decision in favor of OIG. Serono's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Serono upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines

that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Serono may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Serono shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Serono, Serono shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Serono and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Serono;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. The undersigned Serono signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF SERONO HOLDING, INC.

Thomas Gunning, Esq.
Vice President and General Counsel
Serono Holding, Inc.

10/14/05
DATE

John T. Bentivoglio, Esq.
King & Spalding LLP
Counsel for Serono

DATE

ON BEHALF OF SERONO HOLDING, INC.

Thomas Gunning, Esq.
Vice President and General Counsel
Serono Holding, Inc.

DATE

John T. Bentivoglio, Esq.
King & Spalding LLP
Counsel for Serono

10/14/05
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

L Morris

Lewis Morris
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

10/13/05

DATE

APPENDIX A
INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.F of the CIA.

A. IRO Engagement.

Serono shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Serono if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Serono may continue to engage the IRO.

If Serono engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Serono shall submit the information identified in Section V.A.11 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Serono if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Serono may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Educational Sponsorship Review and the Promotional and Product Services Engagement who have expertise in the Federal health care program and FDA requirements applicable to sales, marketing and promotion of pharmaceutical products, and to the sponsorship of Continuing Medical Education activities and other third-party scientific and educational conferences or meetings. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Serono products are reimbursed;

2. assign individuals to design and select the Educational Sponsorship Review and the Promotional and Product Services Engagement samples who are knowledgeable about appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Educational Sponsorship Review and Promotional and Product Services Engagement in accordance with the specific requirements of the CIA, including the Appendices to the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in the Educational Sponsorship Review and the Promotional and Product Services Engagement;

3. respond to all OIG inquires in a prompt, objective, and factual manner; and

4. prepare timely, clear, well-written reports that include all the information required by the CIA and Appendices A and B.

D. IRO Independence/Objectivity.

The IRO must perform the Educational Sponsorship Review and the Promotional and Product Services Engagement in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Serono.

E. IRO Removal/Termination.

1. *Provider*. If Serono terminates its IRO during the course of the engagement, Serono must submit a notice explaining its reasons to OIG no later than 30 days after termination. Serono must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO*. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Serono to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Serono to engage a new IRO, OIG shall notify Serono of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Serono may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Serono shall provide any additional information as may be requested by OIG under this

Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Serono prior to requiring Serono to terminate the IRO. However, the final determination as to whether or not to require Serono to engage a new IRO shall be made at the sole discretion of OIG.

Appendix B to CIA for Serono Holding, Inc.
Promotional and Product Services Engagement

I. IRO Engagement, General Description

As specified more fully below, Serono shall retain an Independent Review Organization(s) (IRO) to perform engagements to assist Serono in assessing and evaluating its systems, processes, policies, and procedures related to sales, marketing, promotion, and product services activities (Promotional and Product Services Engagement). The Promotional and Product Services Engagement shall consist of two components - a systems review (the Promotional and Product Services Systems Review) and a transactions review (the Promotional and Product Services Transactions Review), as described more fully below. Serono may engage, at its discretion, a single entity to perform both components of the Promotional and Product Services Engagement, provided that the entity has the necessary expertise and capabilities to perform both.

The Promotional and Product Services Systems Review shall be a review of Serono's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to sales, marketing, promotion, and product services activities. If there are no material changes in Serono's applicable systems, processes, policies, and procedures during the term of the CIA, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If Serono materially changes its systems, processes, policies, and procedures relating to sales, marketing, promotion, and product services activities, the IRO shall perform an additional Promotional and Product Services Systems Review covering the Reporting Period in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and practices previously reported did not materially change; and 3) a review of the systems, processes, policies, and practices that materially changed.

The Promotional and Product Services Transactions Review shall include two elements: 1) reviews of samples of Control Documents, as defined below in Sections III.A.2; and 2) interviews with sales representatives, supervisory personnel, and others as necessary to investigate any Material Errors. The IRO shall perform the Promotional and Product Services Transactions Review on an annual basis and shall cover each Reporting Period.

Consistent with Section III.F.1.b of the CIA, after the third Reporting Period, the OIG may, at its discretion and upon written request of Serono, permit Serono to perform the Promotional and Product Services Transactions Reviews described in this Appendix B, subject to verification by the IRO. In such an instance, the OIG will provide additional guidance about the exact scope of the IRO's verification review after consultation with Serono. However, at a minimum, the IRO shall review at least 20% of the Sample Units reviewed by Serono in its internal Promotional and Product Services Transactions Review (Verification Review). In addition, as part of Serono's Annual Report, the IRO shall submit a report verifying that the requirements outlined in Section III.F and in Appendices A-B to the CIA have been satisfied and shall report the results, Sample Unit by Sample Unit, of the Verification Review performed. The IRO's report shall identify any discrepancies between the IRO's findings and those of Serono's internal review, and shall identify possible reasons for the discrepancies.

II. Promotional and Product Services Systems Review

A. General Business Policies and Practices for Review

For at least the first and fourth Reporting Periods, the IRO shall review Serono's systems, processes, policies, and procedures associated with the following activities, systems, and policies (Reviewed Policies and Practices):

1) Serono's systems, policies, processes, and procedures applicable to the manner in which Serono representatives handle requests or inquiries relating to off-label uses of Serono products and the manner in which Serono disseminates materials relating to off-label uses and other medical information about its products. This review includes:

(i) the manner in which sales personnel and Medical Information receive and respond to requests for information about off-label uses;
(ii) the form and content of information disseminated by Medical Information;
(iii) Serono's internal review process for the information disseminated by Medical Information;
(iv) Serono's systems, processes, and procedures to track information requests and responses to those requests;
(v) the manner in which Medical Information collects and documents information in the Serostim Inquiry Database;
(vi) the manner in which Medical Information provides Serostim

Inquiry Reports to the Compliance Officer; and
(vii) the internal review of Serostim Inquiry Reports and related processes, procedures, and resolution of any issues identified;

2) Serono's policies and procedures applicable to the manner and circumstances under which medical affairs personnel (including medical science liaisons) participate in meetings or events with physicians, pharmacists, or other health care professionals (HCPs) (either alone or with members of the sales force) and the role of the medical affairs personnel at such meetings or events;

3) Serono's systems, policies, processes, and procedures relating to the retention of HCPs as consultants (*e.g.,* including as members of advisory boards, focus groups, or clinical research project teams) or speakers. This shall include a review of:

(i) the criteria used to determine whether, how many, and under what circumstances (including the venue for the performance of any services) Serono will enter contracts for such arrangements;
(ii) the processes and criteria used to identify and select HCPs with whom Serono enters consultant, speaker, or other contractual arrangements, including the role played by sales representatives in the process. This includes a review of Serono's internal review and approval process for such contracts, and the circumstances under which there may be exceptions to the process;
(iii) Serono's tracking or monitoring of services provided or the work performed by the consultants or speakers (including the receipt of the consultants' work product, if any);
(iv) the uses made of work product received from consultants or speakers, if any;
(v) Serono's processes for establishing the amounts paid to HCPs and the reasons or justifications for any differentials in the amounts paid to different HCPs;
(vi) the criteria used to determine under what circumstances entertainment, recreation, travel, lodging, meals and/or other items or reimbursements are provided to consultants or speakers, and Serono's processes for establishing the amounts reimbursed or the type of entertainment or recreation provided;
(vii) whether and in what manner Serono tracks or monitors the

prescribing habits or product use of individuals or entities with whom it enters consulting, speakers, or other contractual arrangements, if any; and
(viii) the budget funding source within Serono (*e.g.*, department or division) for the consulting or contractual arrangement;

4) Serono's systems, policies, processes, and procedures relating to charitable contributions or sponsorships by Serono. This review shall include a review of the following items:

(i) the processes and procedures used to approve charitable contributions or sponsorships;
(ii) the criteria used to determine whether and under what circumstances the charitable contributions or sponsorships will be provided;
(iii) the processes and criteria used to select and approve recipients of the charitable contributions or sponsorships from Serono, including the role played by sales representatives in the processes (if any), and the circumstances under which there may be exceptions to the processes;
(iv) Serono's policies and procedures related to circumstances, if any, under which the recipient or the recipient's agent is required to disclose Serono's charitable contribution or sponsorship and any financial relationship Serono may have with the recipients;
(v) Serono's policies or procedures for determining and memorializing the amounts paid to recipients of the charitable contribution or sponsorship and the purpose or justifications for the amounts paid;
(vi) Serono's policies and procedures relating to the independence of any programs funded through the charitable contribution or sponsorship;
(vii) Serono's policies and procedures relating to the content and promotional nature of any programs sponsored through the charitable contributions or sponsorships;
(viii) whether and in what manner Serono tracks or monitors the prescribing habits or product use of individuals or entities receiving the charitable contribution or funding, if any; and
(ix) the budget funding source within Serono (*e.g.*, department or division) from which the charitable contributions or sponsorships are

provided;

5) Serono's systems, policies, processes, and procedures relating to funding or sponsoring of research agreements, grants, and/or research collaborations (including clinical trials and independent research) (collectively "Research Activities") entered into or funded by Serono. This review shall include a review of the following items:

(i) the processes and procedures used by Serono to approve Research Activities;
(ii) the criteria used to determine whether, and under what circumstances, Serono will fund or otherwise participate in the Research Activities;
(iii) the processes and criteria used to select and approve the funding or other participation by Serono in Research Activities, including the role played by sales representatives in the processes (if any), and the circumstances under which there may be exceptions to the processes;
(iv) Serono's policies and procedures for requiring the recipient of the funding for the Research Activity to disclose Serono's participation in or funding of Research Activities and any financial relationship Serono may have with the recipient;
(v) Serono's policies or procedures for determining and memorializing the amounts paid to participants in the Research Activities and the purpose or justifications for the amounts paid;
(vi) Serono's policies and procedures relating to the independence of the programs funded through Research Activities;
(vii) Serono's policies and procedures relating to the content and promotional nature of any programs sponsored through or associated with the Research Activities;
(viii) whether and in what manner Serono tracks or monitors the prescribing habits or product use of individuals or entities receiving funding or otherwise participating in the Research Activities, if any; and
(ix) the budget funding source within Serono (*e.g.*, department or division) for the Research Activity;

6) Serono's systems, policies, processes, and procedures relating to the provision of any gifts, meals, receptions, travel, entertainment or other items of value (collectively "Expenses") to HCPs. This shall include a review of:

(i) the criteria used to determine whether, how many, and under what circumstances (including the venue for the performance of any services) Serono will reimburse for Expenses of HCPs;
(ii) the processes and criteria used to identify and select HCPs to whom Serono provides reimbursement of Expenses. This includes a review of Serono's internal review and approval process for such Expenses, the circumstances under which there may be exceptions to the processes, and the role played by sales representatives in the process;
(iii) Serono's tracking or monitoring of services provided, or the work performed by the HCPs in exchange for the Expenses, if any;
(iv) the uses made of work product received from HCPs receiving Expenses from Serono, if any;
(v) Serono's processes for establishing the amounts paid to HCPs and the reasons or justifications for any differentials in the amounts paid to different HCPs;
(vi) whether and in what manner Serono tracks or monitors the prescribing habits or product use of HCPs who receive Expenses from Serono, if any; and
(vii) the budget funding source within Serono (*e.g.*, department or division) for the Expenses;

7) Serono's systems, policies, processes, and procedures relating to: (i) expenditures for third-party advice about reimbursement or claims submission for Serono products; (ii) the provision of or payment for customer or patient assistance programs; and (iii) the provision of debt forgiveness, debt reduction, or other like assistance to customers, purchasers, or prescribers;

8) Serono's systems, policies, processes, and procedures for tracking expenditures (individual and aggregate) associated with the Reviewed Policies and Practices;

9) Serono's policies, processes, and procedures relating to the disciplinary actions that Serono may impose in the event a Covered Person violates a Serono policy or procedure; and

10) Serono's systems, polices, processes and procedures for compensating (including with salaries and bonuses) non-Overtime Eligible employees,

with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate sales and marketing personnel to engage in the improper promotion, sales, and marketing of Serono's products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance.

B. Promotional and Product Services Systems Review Report

The IRO shall prepare a report based upon its Systems Review. For each of the Reviewed Policies and Practices identified in Section II.A above, the report shall include the following items:

a) a description of the documentation (including policies) reviewed and any personnel interviewed;

b) a detailed description of Serono's systems, policies, processes, and practices with regard to the items identified in Sections II.A.1-7 above, including a general description of Serono's control and accountability systems (*e.g.*, documentation and approval requirements, tracking mechanisms) and written policies regarding the Reviewed Policies and Practices;

c) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-7 above are made known or disseminated within Serono;

d) a detailed description of any system used to track and respond to requests for information about Serono's products that come to Medical Information;

e) a description of Serono's systems, policies, processes, and procedures for tracking expenditures associated with the Reviewed Policies and Practices or other promotional activities;

f) a general description of the disciplinary measures Serono has established for failure to comply with its systems, processes, policies and procedures relating to the Reviewed Policies and Practices;

g) a detailed description of Serono's compensation system

(including salaries and bonuses) for non-Overtime Eligible employees, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Serono may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

h) findings and supporting rationale regarding any weaknesses in Serono's promotional and product services related systems, processes, policies, and practices reviewed, if any; and

i) recommendations to improve any of the reviewed promotional and product information related systems, policies, processes, or practices, if any.

Prior to the IRO's submission of the report to the OIG, Serono shall be provided with a copy of the report and an opportunity to respond to each comment made by the IRO. Provided it does not delay the timely filing of the Annual Reports, any responses by Serono may be included in the IRO report submitted to the OIG. Otherwise, any responses by Serono to the IRO's findings may be submitted separately to the OIG following the Annual Report submission.

III. Promotional and Product Services Transactions Review

Except as otherwise provided in Section III.F.1.b of the CIA and in Section I of this Appendix, the IRO shall conduct a Promotional and Product Services Transactions Review for each of the Reporting Periods. The Transactions Review shall include two general elements: (1) reviews of Sample Units of Control Documents associated with certain Reviewed Activities; and (2) interviews with sales representatives, contract sales representatives, managers, and other supervisory personnel relating to any identified Material Errors.

A. Promotional and Product Services Transactions Review

1) Reviewed Activities

For each Reporting Period, the IRO shall review Serono's systems, policies, procedures, and practices pertaining to the following types of activities:

a) retention of HCPs, and other purchasers and/or prescribers of Serono's Products, for speaking arrangements;
b) retention of HCPs, and other purchasers and/or prescribers of Serono's Products, for consulting arrangements;
c) awarding or payment of research grants and the funding or other participation in research activities;
d) awarding or payment of charitable contributions or sponsorships; and
e) provision of gifts, meals, entertainment, recreation or other items to HCPs.

This list of activities shall hereafter be referred to as the "Reviewed Activities."

2) Description of Reviewed Activities Control Documents

For purposes of the Promotional and Product Services Transactions Review, the term "Control Documents" shall mean those documents associated with, or reflecting expenditures, for the Reviewed Activities outlined in Section III.A.1 above. The IRO shall review and evaluate Control Documents associated with these expenditures. By way of example, Control Documents that the IRO may review could include, but are not limited to, the following types of documents:

a) Agreements with HCPs engaged to be speakers for Serono;
b) Agreements with HCPs to provide consulting services;
c) Contracts or agreements relating to sponsorship of Educational Activities;
d) Contracts or agreements relating to research funding;
e) Documents reflecting charitable contributions or sponsorships; and
f) Expense Reports of field sales and marketing personnel.

3) Review of Reviewed Activities Control Documents

The Control Documents associated with each type of Reviewed Activity listed in Section III.A.1 shall be considered a separate universe of Control Documents. Each set of Control Documents relating to a particular instance of a Reviewed Activity shall be referred to as a Sample Unit. For example, all Control Documents associated with a speaking arrangement entered into by Serono and a particular HCP shall be considered a Sample Unit.

For each Reviewed Activity, the IRO shall randomly select and review the following number of Sample Units from each universe:

a) in connection with the Reviewed Activities identified in Section III.A.1.a, 50 Sample Units;
b) in connection with the Reviewed Activities identified in Section III.A.1.b, 50 Sample Units;
c) in connection with the Reviewed Activities identified in Section III.A.1.c, 10 Sample Units;
d) in connection with the Reviewed Activities identified in Section III.A.1.d, 20 Sample Units;
e) in connection with the Reviewed Activities identified in Section III.A.1.e, 50 Sample Units.

For each Sample Unit the IRO shall determine:

i) whether all required Control Documents associated with the Reviewed Activity exist in appropriate files in accordance with Serono's policies;

ii) whether all required Control Documents associated with the Reviewed Activity were completed and archived in accordance with the requirements set forth in Serono's policies; and

iii) whether the Control Documents associated with the Reviewed Activity reflect that all required written approvals were obtained in accordance with Serono's policies.

4) Identification of Material Errors and Additional Engagement

Any Sample Unit that does not satisfy the criteria set forth above in Section III.A.3 shall be considered an exception and shall be so denoted by the IRO. The IRO will consider a Control Document to have a Material Error if either of the following is identified:

a) all the appropriate and required Control Documents relating to a Reviewed Activity do not exist and (i) no corrective action has been taken prior to the IRO review; or (ii) the IRO cannot confirm that Serono has otherwise followed its policies and procedures; or

b) information or data is omitted from key fields in the Control Documents that prevents the IRO from understanding the nature of the expenditure and/or assessing compliance with Serono's Policies and Procedures.

If the IRO finds any Material Errors, it shall conduct an Additional Engagement to review the expenditures or activities reflected in the erroneous Sample Unit. The IRO shall perform this Additional Engagement in a manner designed to determine the root cause of the Material Errors. For instance, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel (*e.g.,* sales representatives, contract sales representatives, managers, and other supervisory personnel) to identify the root cause(s) of the errors.

B. Promotional and Product Services Transactions Review Report

Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a Report based on its Promotional and Product Services Transactions Review. Each Report shall include the following:

1. Elements to Be Included:

a) Promotional and Product Services Transactions Review Objectives: A clear statement of the objectives intended to be achieved by the Review;

b) Engagement Protocol: A detailed narrative description of the procedures performed and a description of the universes of Sample Units from which samples were selected; and

c) Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Promotional and Product Services Transactions Review.

2. Results to Be Included:

The following results shall be included in each Promotional and Product Services Transactions Review Report:

a) a description of each type of Sample Unit reviewed, including the number of each type of Sample Units reviewed (*i.e.,* the number of Sample Units associated with each type of Reviewed Activity) and an identification of the types of Control Documents reviewed for each type of Sample Unit;

b) for each Sample Unit, the IRO shall state its findings and supporting

rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all requirements set forth in the applicable Serono's policy; (iii) each Control Document reflects that Serono's policies were followed in connection with the underlying activity reflected in the document (*e.g.*, all required approvals were obtained); and (iv) any disciplinary action was taken in those instances in which a Serono policy was not followed;

c) for each Sample Unit reviewed, the IRO shall identify and describe all exceptions discovered. The IRO shall describe those situations where corrective action was taken prior to the IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action. The IRO shall also describe the situations in which it attempted to confirm whether Serono otherwise followed its policies and procedures, and the steps undertaken by the IRO to make that determination;

e) if any Material Errors were discovered for any Sample Unit, the IRO shall describe the Material Error in detail and the additional review procedures it performed, including any interviews conducted. The IRO shall state its findings as to the root cause of each Material Error(s);

f) the findings and supporting rationale regarding any weaknesses in Serono's systems, processes, policies, and practices relating to the Reviewed Activities, if any; and

g) recommendations for improvement in Serono's systems, processes, policies, and practices relating to the Reviewed Activities, if any.